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EXAMINER	
SAOUD, CHRISTINE J	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/039,050	COLLIER ET AL.	
	Examiner	Art Unit	
	Christine J. Saoud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-86* is/are pending in the application.

4a) Of the above claim(s) *2-9,14-17,21-49,51-58,63-66 and 70-86* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,10-13,18-20,50,59-62 and 67-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *08/28/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II, claims 10-13, 18-20, 59-62, and 67-69, drawn to polynucleotides of SEQ ID NO:5 and 9 that encode the polypeptide of SEQ ID NO:6 in the paper filed 09 February 2005, is acknowledged. The traversal is on the ground(s) that (1) without a showing of independence and distinctness, a restriction requirement is unauthorized, (2) Groups I-XIX are all different aspects of a single invention, (3) MPEP 803.04 states that "up to ten independent and distinct nucleotide sequence will be examined in a single application without restriction", (4) Groups I-IV are classified in the same class and subclass, (5) "reliance on the supposed classification of the groups of claims does not establish independence and distinctness" and the "classification system has no statutory recognition of evidence of whether inventions are independent and distinct", (6) due to fee requirements, restriction requires excessive filing costs and compromises the term of related patent assets, (7) all 19 groups must be patentably distinct in order for the restriction to be made final. Each ground of traversal will be addressed separately.

(1) MPEP 802.01 makes clear that even though 35 U.S.C. 121 states "independent and distinct", "The law has long been established that dependent inventions (frequently termed related inventions) ... may be properly divided if they are, in fact, "distinct" inventions, even though dependent". Inventions which are related are considered distinct if they are capable of separate manufacture, use, or sale as claimed and are patentable (i.e. novel and obvious) over each other. MPEP 803 additionally

states "Under the statute an application may properly be required to be restricted to one of two or more claimed invention only if they are able to support separate patents and they are either independent or distinct". Therefore, Applicant's statements that the claimed inventions have not been shown to be both "independent and distinct" is moot since this is not the requirement as supported by the passages cited from the MPEP, based on the law.

(2) Applicant's statements that the identified inventive Groups I-XIX are "different aspects of a single invention" are not persuasive. As pointed out in the previous Office action, the different inventive groups are either independent or distinct for the reasons of record. Since the distinct inventions would be patentable over each other and support separate patents, restriction is proper.

(3) With regard to MPEP 803.04, this section of the MPEP begins by indicating "Nucleotide sequence encoding different proteins are structurally distinct chemical compounds and are unrelated to one another." "Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 *et seq.*" Since MPEP 803.04 does not state that 10 sequences will be examined (language used is "up to 10"), fewer than 10 sequence may also be examined. In the instant situation, 2 distinct sequences (SEQ ID NO:5 and 9) are being examined, as well as all sequences that encode SEQ ID NO:6; this is more than 10 sequences. Applicant may petition pursuant to 37 CFR 1.181 for examination of additional nucleotide

sequence by providing evidence that the different nucleotide sequences do not cover independent and distinct inventions.

(4) With regard to common classification of Groups I-IV, such common classification does not preclude restriction. Class 536, subclass 23.4 includes all DNA or RNA which encode fusion proteins. One of ordinary skill in the art would not argue that all DNA or RNA encoding fusion proteins are directed to the same invention, and therefore, not patentable over one another. Classification is one means to indicate that inventions are distinct and can support separate patents. In the instant case, the inventions are related in that they are all polynucleotides, however, the polynucleotides in each group are distinct because they do not share a common structural feature (i.e. sequence or encoding a common protein). Therefore, a search of one invention would not reveal art on the other claimed inventions, and therefore, there is a burden of search and restriction is proper.

(5) Applicant's comments on the classification system would be better addressed to the USPTO management.

(6) The issue of fees and cost of patent prosecution to applicant are not mentioned in 37 CFR 1.141 or in 35 U.S.C. 121, and therefore are not a matter to be discussed with regard to the propriety of the restriction requirement.

(7) Applicant is incorrect; the 19 identified inventions must be shown to be either independent or distinct. The Examiner met this burden in the previous Office action, and therefore, the restriction is proper.

Claims 2-9, 14-17, 21-49, 51-58, 63-66, 70-86 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 09 February 2005.

The requirement is still deemed proper and is therefore made FINAL.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

It is noted that this application appears to claim subject matter disclosed in prior Application No. 60/141,441, filed 29 June 1999. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. Also, the current status of all nonprovisional parent applications referenced should be included.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the

national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other

information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

The disclosure is objected to because of the following informalities: the specification fails to comply with the sequence rules, 37 CFR 1.821(d). This portion of the rules states "Where the description or claims of a patent application discuss a sequence that is w4et forth in the "Sequence Listing" in accordance with paragraph(c) of this section, reference msut be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application." Applicant's use of "numeric identifiers" such as "<400>" is not proper and not in compliance with the above stated rule. The entire specification should be amended to correct this deficiency.

Appropriate correction is required.

Drawings

The drawings are objected to because they are not in compliance with 37 CFR 1.84(u)(1) as well as being objected to for including blank pages (i.e. pages with no data, only reference to the subparts of the figure which are not present). Corrected

drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 10-13, 18-20, 50, 59-62, 67-69 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility.

The instant specification asserts that the claimed invention is directed to "nucleic acid molecules encoding proteins associated with the modulation of obesity, diabetes and/or metabolic energy levels" (see page 1, lines 16-17). The specification provides for 3 nucleic acid molecules which are expressed at a higher level in liver tissue of obese or fed animals compared to lean or fasted animals. The specification contemplates "therapeutic and prophylactic uses" for the encoded protein and nucleic acid molecules (see page 12, lines 29-31), but does not indicate what those uses would be. The specification contemplates modulating expression of the claimed nucleic acid molecule(s) and modulating activity of the encoded protein, but does not indicate what purpose this modulation would serve and likewise does not indicate what activity would be modulated. The specification further contemplates treating a mammal suffering from obesity, anorexia, diabetes and/or energy imbalance (see page 13, lines 11-13) by administration of an agent that would modulate the nucleic acid or the activity of the encoded protein.

The instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby wherein the nucleic acid is more highly expressed in liver tissue from obese or fed animals compared to lean or fasted animals. The instant specification asserts use of the claimed invention with regards to obesity, diabetes and metabolic conditions as summarized above. The specification does not provide for any biological activity of the encoded protein or provide any nexus between the claimed nucleic acid molecules and any disease, condition or biological effect.

These utilities are not considered to be specific and substantial because the specification fails to disclose any particular function or biological significance for the claimed nucleic acid of the instant invention. The claimed invention is asserted to play a role in obesity, diabetes and/or energy metabolism based on its expression pattern in obese/fed animals compared to lean/fasted animals. However, the instant specification fails to provide any nexus between the claimed nucleic acid molecule and any disease, condition or aspect of energy metabolism. After further research, a specific and substantial credible utility might be found for the claimed invention. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete.

The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-tumor activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately apparent or fully disclosed "real world" utility. The court held that:

> The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benefit exists

> in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field. . . . a patent is not a hunting license. . . .[i]t is not a reward for the search, but compensation for its successful conclusion.

The instant claims are drawn to a nucleic acid of as yet undetermined function or biological significance. There is no evidence of record or any line of reasoning that would support a conclusion that the nucleic acid molecule of the instant application was, as of the filing date, useful for treating any condition related to obesity, anorexia, diabetes or energy imbalance or that the claimed nucleic acid molecule plays any role in these conditions at all. Until some actual and specific significance can be attributed to the claimed nucleic acid molecule, one of ordinary skill in the art would be required to perform additional experimentation in order to determine how to use the claimed invention. Thus, there was no immediately apparent or "real world" utility as of the filing date.

A nucleic acid sequence search of the claimed invention (SEQ ID NO:5, 9 and encoded protein SEQ ID NO:6) revealed that the encoded protein appears to be a selenoprotein (see Kryukov et al. Science 300: 1439-1443). Selenoproteins are thought to be responsible for most biomedical effects of dietary selenium. However, there is no evidence of record which would suggest that the claimed invention, or selenoproteins, have anything to do with obesity, anorexia, diabetes or energy imbalance. The specification fails to establish a nexus between the claimed invention and obesity, anorexia, diabetes or energy imbalance, and therefore, the asserted utilities related to such are not substantial.

In the absence of knowledge of the biological significance of the claimed nucleic acid or its encoded protein, there is no immediately evident patentable use for it. To employ the claimed nucleic acid or the encoded protein of the instant invention in any of the disclosed methods or asserted uses would clearly be using it as the object of further research. Such a use has been determined by the courts to be a utility which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for the claimed nucleic acid, then the claimed invention as disclosed does not meet the requirements of 35 U.S.C. §101 as being useful.

Claims 1, 10-13, 18-20, 50, 59-62, 67-69 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1, 10-13, 18-20, 50, 59-62, 67-69 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 and 50 are directed to nucleic acid molecules wherein there is no recitation of structure for the molecules being claimed. This is reminiscent of a single means claim where the claim covers every conceivable structure (means – in this case nucleic acid) for achieving the stated property (result – in this case, greater expression levels in a particular tissue) while the specification discloses at most only those known to the inventor. See MPEP 2164.08(a) and *In re Hyatt*, 708 F.2d 712, 714-715, 218 USPQ 195, 197 (Fed. Cir. 1983). The specification only discloses 3 molecules, and therefore, the claims are not commensurate in scope with the disclosure of the instant specification.

The claims are drawn to nucleic acids with no structure (claims 1 and 50), which encode proteins or derivatives, homologues, mimetics, with no activity or structure (claims 1 and 50), which have 45% similarity to 10 contiguous amino acids in a disclosed sequence, which are substantially as set forth in a particular sequence, and which hybridize under low stringency conditions. The claims do not require that the nucleic acid encode a protein that possesses any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of nucleic acids that are defined by expression pattern or some degree of sequence identity.

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to

be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, some of the claims have partial structure and some have no structure at all. In the claims with partial structure, it is not clear what structure is present because of the recitation "substantially as set forth" (see rejection below). There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated nucleic acids of SEQ ID NO:5 and 9, or encoding SEQ ID NO:6, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 10-13, 18-20, 50, 59-62, 67-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10-13, 18-20, 59-62, 67-69 indicate that the claimed nucleic acids possess sequences "substantially as set forth". This recitation is indefinite because it is not clear what portion of the sequence is important to the invention, so it is not clear what the "substantial" portion would be. This issue is complicated by the fact that there is no disclosed activity which would would like to retain, and possibly define the substantial portion. Therefore, the claims are indefinite because the metes and bounds of the claims cannot be determined.

Claims 10-13, 19, 59, 61, 68 are indefinite for the recitation of "having at least about 45% similarity". The recitation of "at least" would normally set a lower limit for the range which is being claimed. However, the inclusion of "about" with the recitation of "at least" is indefinite because the range which is being claimed cannot be determined since there is no definite lower limit anymore.

Claims 11, 18, 60, 67 require "low stringency" hybridization. However, hybridization conditions are variable depending on a number of variables which are present in the process. Furthermore, there are a multitude of conditions which would equate to low stringency in the art based on temperature, salt, wash conditions, probe length, etc. Therefore, without a recitation of which conditions are intended by the language "low stringency", the metes and bounds of the claims cannot be determined.

Claims 1, 10-13, 18-20, 50, 59-62, 67-69 are refer or depend on claims which use the language derivative, homologue, mimetic, and/or analogue. However, the use of these terms render the claims indefinite because the metes and bounds of what is being claimed cannot be determined. For example, the use of the term mimetic implies that the molecule being claimed possesses the same activity as the molecule it is a mimetic of. However, the instant specification fails to provide any activity for the encoded protein, so one cannot envision a mimetic and the metes and bounds of what is being claimed cannot be determined. This rationale is similar for derivatives, homologues and analogues as there is an implied structural relationship as well as functional relationship. Without a known function, the metes and bounds of what would be a derivative, homologue, mimetic and/or analogue cannot be determined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 10-13, 18-20, 50, 59-62, 67-69 are rejected under 35 U.S.C. 102(e) as being anticipated by Rosen et al. (US 2002/0055627).

Rosen et al. disclose a nucleic acid which is 100% identical to SEQ ID NO:5 (see SEQ ID NO:140). The nucleic acid of Rosen et al. does not disclose the encoded protein, however, since the coding region is a property of the claimed nucleic acid, and the nucleic acid of Rosen et al. is 100% identical, this property would also be possessed by the molecule of the prior art. Rosen et al. does not teach a nucleic acid molecule which is 100% identical to the molecule of SEQ ID NO :9 of the claims, however, the molecule of Rosen et al. would be expected to hybridize under low stringency conditions because nucleic acid molecules are inherently sticky and in the absence of what conditions are intended by the claims, "low stringency conditions" generally allow for nucleic acid molecules to stick together. Since there are "substantial" portions of SEQ ID NO:9 that are identical (i.e. coding regions), hybridization would be expected to occur

at low stringency. Lastly, the molecule of Rosen et al. also appears to be "substantially as set forth in SEQ ID NO:9" and, therefore, anticipates the claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on mttr, 8:00-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine J. Saoud